

REMARKS/ARGUMENTS

Upon entry of the current amendment, Claims 1-3, 16-17, 21-22, and 24-32 are currently pending in the present application, with new claim 32 being added hereby. The Examiner has rejected claims 1-3, 16-17, 21-22, and 24, and objected to claims 25-31 as being dependent upon a rejected base claim. Applicants address the Examiner's comments in the order made.

Support for new claim 32 may be found in the specification at paragraph 73, which reads in relevant part: "In some embodiments, the nucleic acid does not also comprise one or more of ... *megCII* ... or *megY*."

1. The Examiner has rejected claims 21-22 pursuant to 35 U.S.C. 112, first paragraph, because the specification allegedly lacks adequate guidance to enable a skilled artisan to practice the claimed invention commensurate in scope with the claims.

Applicants have amended claim 21, as suggested by the Examiner, to clarify that the recombinant cell is "transformed with" the nucleic acid of claim 1. Because claim 22 depends from claim 21, the Examiner's rejection of both claims 21 and 22 is addressed by the current amendment.

2. The Examiner has rejected claims 21-22 pursuant to 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter which applicants regard as their invention. Specifically, the Examiner cites a lack of antecedent basis for the term "the unmodified polyketide." Applicants have amended claim 21 to read "an unmodified polyketide" to address the Examiner's comments. Because claim 22 depends from claim 21, the Examiner's rejection of both claims 21 and 22 is addressed by the current amendment.

3. The Examiner has rejected claims 1-3, 16-17, 21-22, and 24 as allegedly being anticipated under 35 U.S.C. 102(b) by Volchegursky et al. 2000 *Molecular Microbiology* 37(4):752-762 (hereinafter "Volchegursky"), and under 35 U.S.C. 102(e) by US Patent No. 6,524,841 to McDaniel et al. (hereinafter "the '841 patent").

The Examiner's comments regarding the two references pertain to the disclosure of two cosmids, KOS079-138B and KOS079-124B, which are disclosed with partial sequences in both Volchegursky and the '841 patent.

The Examiner alleges that the two cosmids inherently disclose the nucleic acids comprising the claimed polyketide modifying genes and therefore anticipate claims 1-3, 16-17, 21-22, and 24 of the present application. However, the cosmids disclosed in Volchegursky and the '841 patent were not publicly available at the filing date of the instant application. As the Office is aware, a prior art reference must be enabling to anticipate an invention. Because the cosmids were not available, the prior art disclosure is not enabling and cannot anticipate the claimed invention.

"In order to be anticipating, a prior art reference must be enabling so that the claimed subject matter may be made or used by one skilled in the art." *Impax Laboratories Inc. v. Aventis Pharmaceuticals Inc.* 81 USPQ2d 1001 (Fed. Cir. 2006) (citing *Amgen Inc. v. Hoechst Marion Roussel, Inc.* 65 USPQ2d 1385 (Fed. Cir. 2003)). Prior art is not enabling if it does not enable a person of ordinary skill in the art to carry out the invention without undue experimentation. *Impax Laboratories, Inc.*, supra. Moreover, "prior art ... must sufficiently describe the claimed invention to have placed the public in possession of it." *In re Donohue* 226 USPQ 619 (Fed. Cir. 1985).

Neither the genes recited in claim 1 nor their nucleotide sequences are disclosed in the references. Applicants submit that without knowledge of the existence, location, structure, or sequence of the genes, and without access to the cosmids disclosed in the references, a skilled person would not have been able to make or use the nucleic acids now claimed. As such, neither Volchegursky nor the '841 patent are enabling with respect to the present claims and cannot, therefore, anticipate the claimed invention.

4. The Examiner has objected to claims 25-31 as depending from a rejected base claim. Applicants have rewritten claims 25 and 28 in independent form, including all of the limitations of the claims from which they formerly depended. In addition, applicants have amended claims 26 and 27 to depend from amended claim 25, and corrected a typographical

error in claim 29. Applicants submit that these amendments address the Examiner's objections and place the claims in condition for allowance.

5. Finally, applicants have added new claim 32, which comprises a nucleic acid of claim 1, but which excludes a gene encoding MegY or MegCII. Applicants submit that given the absence of specific knowledge of the genes or the corresponding nucleotide sequences of claim 1 in the prior art, it would not have been possible for one skilled in the art, even assuming *arguendo*, a sufficient motivation, to manipulate the prior art sequences to produce nucleic acids as claimed in new claim 32. MegY and MegCII are described in the '841 patent (e.g., Figure 9) and in Volchegursky (e.g., Figure 3), MegY being just upstream of MegDII, and MegCII being just downstream of MegCI.

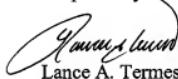
The exclusion of MegY or MegCII from the nucleic acids of the present application make them distinct from the cosmids of Volchegursky and the '841 patent, which do not concurrently include a polyketide modifying gene encoding a polyketide modifying enzyme selected from MegR, MegCIV, MegCV, MegBVI, MegBIII, MegL, and MegM, and exclude MegY or MegCII. Because the cosmids of Volchegursky and the '841 patent are distinct from the claimed nucleic acids they cannot anticipate new claim 32.

CONCLUSION

In view of the foregoing, applicants respectfully submit that the rejections should be withdrawn.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 650-326-2400.

Respectfully submitted,



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